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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,479	07/23/2004	Patrick Wuthrich	SERVIER 427 PCT	4008

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THE FIRM OF HUESCHEN AND SAGE
SEVENTH FLOOR, KALAMAZOO BUILDING
107 WEST MICHIGAN AVENUE
KALAMAZOO, MI 49007

EXAMINER	
MERCIER, MELISSA S	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
03/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,479	WUTHRICH ET AL.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-23-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of the Preliminary Amendment is acknowledged. Claims 11-23 are pending in this application.

Priority

Applicants Claim of Priority to PCT/FR03/00200 filed on January 22, 2003 is acknowledged.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on July 23, 2004 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has not provided adequate written description of the broad claim of flow agent. A review of Applicants specification discloses one example, colloidal silica. The disclosure of only one example does not disclose structural or functional linkages in order for one of ordinary skill in the art to distinguish what would be considered a flow agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if applicant is claiming one or more lubricants, or one or more lubricants OR flow agents.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serpelloni (US Patent 7,201,922).

Serpelloni discloses an orodispersible solid pharmaceutical form characterized in that it comprises granules consisting of lactose and starch which have been codried, and at least one active substance. The solid dosage form has a hardness measured to be between 30-300 newtons (column 4, lines 28-32) Additionally, the active substances may be chosen from a large number of pharmaceutical active agents intended for oral administration, and in particular from the group consisting of analgesics, antipyretics, antidiarrheals, antispasmodics, antiinfectious agents, antibiotics, antivirals, antiparasitics, digestive motility regulators, blood pressure regulators, cardiac and coronary insufficiency regulators, cardiac rhythm regulators, central nervous system regulators, lipid, carbohydrate and protein metabolism regulators, bone metabolism regulators, vasculoprotective and venotonic agents, hormone and immune system regulators, steroidal and nonsteroidal anti-inflammatory agents, antihistamines and antiallergics, antiasthmatics, antitusives, expectorants, mucoregulators, antiemetics, diuretics, laxatives, cytotoxics and cytostatics, vitamin and mineral elements, plant extracts (column 4, lines 39-55).

The term or dispersible is defined to mean solid dosage forms which disintegrate in the buckle cavity in less than 3 minutes and preferably less than 1 minute, as claimed in claims 11-12 (column 3, lines 30-32).

Regarding claim 14, the active agent is present from 0.2-95% of the composition (column 5, lines 15-19). The granules have a lactose/starch ratio of between 90/10 and 25/75 (column 5, lines 22-24) and are present from about 20-99% of the dosage form (column 5, lines 31-35).

Regarding claim 16, all examples disclose the use of magnesium stearate, which the specification discloses as the preferred lubricant (Examples).

Regarding claims 17-18, the dosage form is disclosed to include tablets formed from direct compression (column 1, lines 34-36; Examples).

Regarding claim 19-20, Serpelloni discloses the solid dosage forms obtained have an orodispersibility which is quite remarkable, regardless of their hardness and density. Indeed, the use of lactose and starch granules in accordance with the invention allows the formulator to choose from a very broad panel of parameters for manufacturing solid dosage forms while being assured to finally obtain a dosage form which is not very brittle, which disintegrates very rapidly in the mouth, which was not allowed by the prior art excipients intended for fast release dosage forms. Furthermore, the properties of the said granules allow the formulator to dispense with the addition of a superdisintegrant to the tablet formula, which is very advantageous from the technical and economic point of view. The use according to the invention of codried granules consisting of lactose and starch in the manufacture of orodispersible dosage forms which disintegrate in the mouth in less than one minute is therefore particularly innovative (column 5, lines 43-60). It is therefore the position of the examiner that one of ordinary skill in the art would have the knowledge and ability to optimize the hardness of the tablets to meet the needs and functional properties desired.

A method of making the dosage form, as recited in claims 21-22, is also disclosed (abstract).

The specific use of perindoril, as an active agent, is not disclosed. However, Serpelloni discloses broad classes of drugs suitable for use in the dosage form. It would have been obvious to a person of ordinary skill in the art to have used any particular active agent in the dosage form in order to obtain the desired effects and properties of such an active agent, in order to obtain a tablet which in the presence of saliva reduce the tablet to small size which is easy to swallow and allow for the immediate release of active agent allowing for the rapid availability in the body as compared with dosage forms to be swallowed by increasing the surface area for exchange with physiological fluids (column 1, lines 52-64).

Regarding claim 23, perindopril is a known antidepressant and known sleep inducer, therefore it would have been within the knowledge of one of ordinary skill to administer the perindopril for the lowering of blood pressure.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615